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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/774,171 | 02/01/2001 | Jeffrey Dickinson | 108129-00004 | 6529 |

6449 7590 04/06/2004

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EXAMINER

SPEAR, JAMES M

| | |
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| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/774,171

Applicant(s)

DICKINSON ET AL.

Examiner

James M Spear

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by On US 6,319,514 B1. The claims remain rejected for the reasons set forth in Paper No. 16, mailed July 14, 2003. While applicants have amended claim 25 to show the amount of domperidone of 0.1 to 20 % by weight, this limitation does not constitute a patentable distinction. The reference shows the particular combination of ibuprofen and domperidone, which has gastric motility stimulating activity to enhance absorption of the ibuprofen. One skilled in the art would envision effective amounts of domperidone to elicit the desired stimulating activity.
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 25-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over On US 6,319,514 B1. The reference shows the particular composition comprised of ibuprofen and domperidone as explained above. The reference does not show the amount by weight of domperidone 0.1 to 20 %. The reference does show conventional granulating agents, lubricants, diluents and other carrier materials utilized in formulating oral dosage forms, such as tablets and capsules. Column 4, lines 15-48. One skilled in the art would readily determine suitable combinations of said carrier materials used to

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process conventional dosage forms. While the reference does not show the amount of domperidone, it would be reasonable for one skilled in the art with a knowledge of the effect domperidone has on gastric motility to determine adequate amounts of domperidone to use in conjunction with ibuprofen without undue experimentation. It would have been obvious to one of ordinary skill in the art to arrive at the amount of domperidone to use with ibuprofen. The motivation being a desire to provide optimum pain relief while minimizing adverse gastrointestinal effects because domperidone has anti-emetic properties. Column 3, lines 14-21.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James M. Spear

JAMES M. SPEAR
PRIMARY EXAMINER
04-01-04

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